PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 5/00 — A1

(11) International Publication Number: **WO 99/05960**

(43) International Publication Date: 11 February 1999 (11.02.99)

(21) International Application Number: PCT/CA97/00544

(22) International Filing Date: 30 July 1997 (30.07.97)

(71) Applicant: UNIVERSITE DE MONTREAL [CA/CA]; 2900 Édouard–Montpetit, Montreal, Quebec H3T 1J4 (CA).

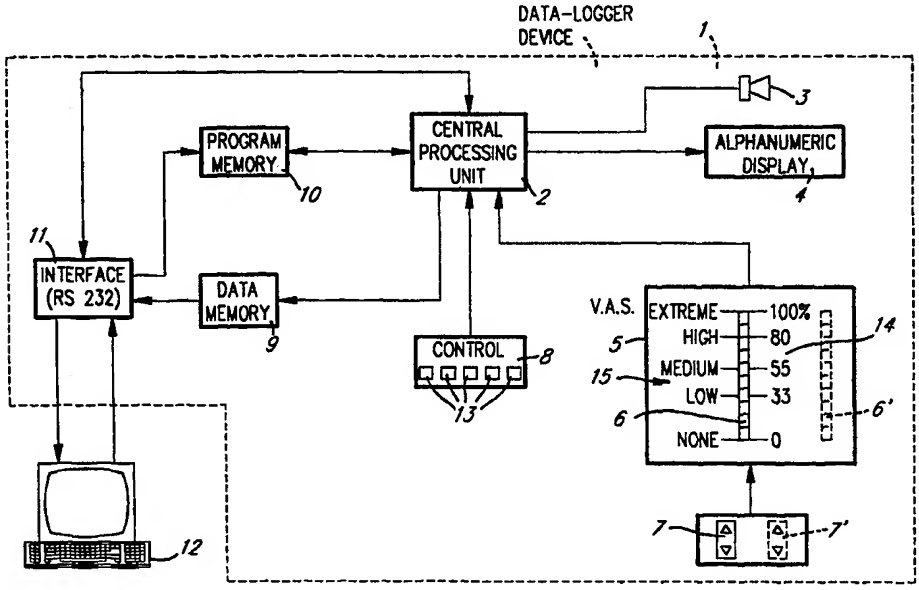
(72) Inventors: DAIGLE, Serge; 301 Lauzon, Rouyn Noranda, Quebec J9X 3T8 (CA). MARCHAND, Serge; 11 MacDonald, Rouyn Noranda, Quebec J9X 1A3 (CA). BUSHNELL, Catherine; 772 A Bloomfield, Outremont, Quebec H2V 3S3 (CA). LAVIGNE, Gilles; 319 Monmouth, Ville Mont–Royal, Quebec H2P 2B3 (CA). SAINT–JACQUES, Sylvain; 808 Rabelais, Deux–Montagnes, Quebec J7R 6S2 (CA).

(74) Agents: DUBUC, Jean, H. et al.; Goudreau Gage Dubuc & Martineau Walker, The Stock Exchange Tower, Suite 3400, 800 Place Victoria, P.O. Box 242, Montreal, Quebec H4Z 1E9 (CA).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: PORTABLE AND PROGRAMMABLE INTERACTIVE VISUAL ANALOGUE SCALE DATA–LOGGER DEVICE



(57) Abstract

A portable, interactive clinical data–logger device signals to a patient under investigation a succession of recording time periods spaced apart by predetermined time intervals. After a recording time period has been signalled, questions such as "What intensity of pain are you feeling ?", "What degree of discomfort are you feeling ?" or "How severe is a given symptom ?" are displayed. The patient answers each question by means of a pushbutton–controlled bar graph associated to a pain intensity, discomfort degree and/or symptom severeness representative V.A.S. scale. The V.A.S. data are then stored and available for further processing into an outside computer.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

PORTABLE AND PROGRAMMABLE INTERACTIVE VISUAL ANALOGUE SCALE DATA-LOGGER DEVICE

BACKGROUND OF THE INVENTION

1. Field of the invention:

The present invention relates to a portable clinical data-logger device of the visual analogue scale (V.A.S.) type to be carried by the patient. This data-logger device is both interactive and programmable, and finds wide applicability in research and clinical practice.

2. Brief description of the prior art:

The company **Autenta AB**, Box 9028, S-750 09 Uppsala, Sweden is fabricating and commercializing a data-logger of the above type, under the name SYMTRACK®. The SYMTRACK® data-logger is portable and carried by the patient to record the intensity/severity of a given symptom in time.

The SYMTRACK® data-logger emits a signal to remind the patient of each recording procedure. User selectable sample periods of 1, 5 or 10 minutes are available.

At each recording, the patient indicates by means of a visual analogue scale (V.A.S.) the intensity/severity of the symptom. Corresponding symptom data are then recorded and available for analysis purposes.

By concealing previous recordings from the patient, the SYMTRACK® data-logger prevents the patient to enter symptom data retrospectively. As retrospective symptom data are notoriously inaccurate, the SYMTRACK® data-logger substantially improves the accuracy of the collected data.

The SYMTRACK® data-logger presents the following drawbacks:

- programming is limited (for example, a very limited number of user selectable sample periods are available);

- data relative to only one symptom can be recorded at a time.

OBJECTS OF THE INVENTION

An object of the present invention is therefore to provide a portable visual analogue scale data-logger device which is fully programmable.

Another object of the present invention is to provide a portable visual analogue scale data-logger device which is interactive to enable recording at the same time of different types of clinical data.

SUMMARY OF THE INVENTION

More specifically, in accordance with the present invention, there is provided a portable, interactive data-logger device for recording clinical data relative to a patient under investigation, comprising:

timer means for signalling to the patient a succession of recording time periods spaced apart by predetermined time intervals;

means for communicating a message to the patient after a recording time period has been signalled;

data-entering means for allowing the patient to enter clinical data relative to the patient and related to the message; and

memory means for receiving and storing the entered clinical data.

In accordance with preferred embodiments of the portable, interactive data-logger device of the invention:

- the message communicating means comprises a display unit for displaying a question to be answered by the patient;

- the portable, interactive data-logger device further comprises means for turning the data-logger device on, the message communicating means then comprising means for communicating a message to the patient following turning on of the data-logger device;

- the portable, interactive data-logger device further comprises means for preventing the patient to enter or alter any data entered during one

recording time period after this recording time period has elapsed;

- the message asks to the patient what intensity of pain he is feeling, what degree of discomfort he is feeling, and/or how severe is a given symptom, the data-entering means comprises means for allowing the patient to enter the intensity of pain he is feeling, the degree of discomfort he is feeling and/or the severeness of the given symptom;

- the data-entering means comprises a bar graph, scale means along the bar graph, and pushbutton means for controlling the bar graph;

- the time intervals between the successive recording time periods and the message to be communicated to the patient after a recording time period has been signalled are fully programmable; and

- the message communicating means comprises means for communicating to the patient a plurality of messages, and the data-entering means comprises means for allowing the patient to enter clinical data related to each message.

The objects, advantages and other features of the present invention will become more apparent upon reading of the following non restrictive description of a preferred embodiment thereof, given by way of example only with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In the appended drawings:

Figure 1 is a schematic block diagram of the preferred embodiment of the portable and programmable interactive visual analogue scale (V.A.S.) data-logger device according to the invention, comprising a central processing unit, an electroacoustic transducer, an alphanumeric display, a V.A.S. including a bar graph controllable through an up/down pushbutton switch, a control keyboard, a data memory, a program memory and an RS 232 port interface; and

Figure 2 is a flow chart showing operation of the portable and programmable interactive visual

analogue scale (V.A.S.) data-logger device of Figure 1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to Figure 1 of the appended drawings, the portable and programmable interactive visual analogue scale (V.A.S.) data-logger device 1, hereinafter referred to as "data-logger device 1" comprises:

- a central processing unit 2;

- an electroacoustic transducer 3 connected to the central processing unit 2;

- an alphanumeric display 4 connected to the central processing unit 2;

- a V.A.S. unit 5 connected to the central processing unit 2 and including a bar graph 6 controllable through an up/down pushbutton switch 7;

- a control keyboard 8 comprising a plurality of keys 13 and connected to the central processing unit 2;

- a data memory 9 connected to the central processing unit 2;

- a program memory 10 in bidirectional communication with the central processing unit 2; and

- an RS 232 port interface 11 connectable to an outside personal computer 12 to establish bidirectional communication between the personal computer 12 and the central processing unit 2, unidirectional communication from the personal computer 12 to the program memory 10 and unidirectional communication from the data memory 9 to the personal computer 12.

Reference will now be made to both Figures 1 and 2 to describe operation of the data-logger device 1.

The data-logger device 1 is programmed (step 20 of Figure 2) for recording clinical data relative to a patient under investigation. Programming is carried out by means of the personal

computer 12 through the RS 232 port interface 11. More specifically, the personal computer 12 communicates with the central processing unit 2 to store the new program in the memory 10.

In particular, successive recording time periods spaced apart by predetermined time intervals are programmed along with questions to be answered by the patient at each recording time period. Different questions may be asked to the patient at successive recording time periods, and the time intervals between the successive recording time periods is programmable at will.

Examples of questions that can be asked to the patient are the following:

- What intensity of pain are you feeling?;

- What degree of discomfort are you feeling?;

- How severe is (a given symptom) ?;

- etc.

A timer is incorporated in the central processing unit 2 to allow this central processing unit 2 to signal to the patient each recording time period (step 21 of Figure 2). This is carried out by the central processing unit 2 by emitting a sound signal through the electroacoustic transducer 3.

In response to the sound signal emitted through the electroacoustic transducer 3, the patient should turn the data-logger device 1 on (step 22 of Figure 2) by depressing one of the keys 13 of the control keyboard 8.

Each recording time period has a given length. After a recording time period has been signalled, the central processing unit 2 counts time. After the recording time period has elapsed (step 23 of Figure 2) the program returns to step 21 and the patient is no longer enabled to enter and/or alter any data related to this particular recording time period. A corresponding message is then displayed (step 24 of Figure 2) on the alphanumeric display 4. This prevents the patient to enter data retrospectively, retrospective data being as mentioned in the foregoing description notoriously inaccurate.

As long as the recording time period has not elapsed (step 23 of Figure 2), the patient is enabled to enter data. It should be pointed out here that the length of the recording time periods is well sufficient to allow the patient to enter the clinical data related to the questions.

If the recording time period is not elapsed, the central processing unit 2 is responsive to turning on of the data-logger device 1 to display on the alphanumeric display 4 a message, in particular but not exclusively a question to be answered by the patient (step 25 of Figure 2).

For example, if the question is "What intensity of pain are you feeling?", the patient operates the up/down pushbutton switch 7 (step 26 of Figure 2) to control the bar graph 6 so as to indicate the intensity of pain he is feeling on the 0-100% scale 14 (Figure 1) appearing along that bar graph 6. To facilitate answering by the patient, indications such as NONE, LOW, MEDIUM, HIGH and EXTREME (see 15 in Figure 1) are distributed along the scale 14.

The patient then depress an "ENTER" key (step 27 of Figure 2) amongst the keys 13 of the keyboard 8 to command the central processing unit 2 to

store or record in the memory 9 the V.A.S. data indicative of the intensity of the pain the patient is feeling (step 28 of Figure 2).

If the patient has to answer another question (step 29 of Figure 2) in the same recording time period, the program of the central processing unit 2 returns to step 25 and steps 25-28 are repeated for the additional question. Therefore, many questions may be asked to the patient during each recording time period.

As another example, if the question is "What degree of discomfort are you feeling?", the patient operates the up/down pushbutton switch 7 to control the bar graph 6 so as to indicate the degree of discomfort he is feeling on the 0-100% scale 14 (Figure 1) taking into consideration the indications 15.

The questions "What intensity of pain are you feeling?" and "What degree of discomfort are you feeling?" can be combined and the V.A.S. unit provided with two bar graphs 6 and 6' respectively controlled through up/down pushbutton switches 7 and 7'. To answer, the patient operates the up/down pushbutton switches 7 and 7' to indicate the intensity of pain

through the bar graph 6 and the degree of discomfort he is feeling through the bar graph 6', that is on the 0-100% scale 14 (Figure 1) taking into consideration the indications 15. Depression of the "ENTER" key of the keyboard 8 (step 27) will then cause recording of both V.A.S. data (step 28) related to the intensity of pain and degree of discomfort.

Another possible question is "How severe is (a given symptom) ? ". Again, to answer that question the patient operates the up/down pushbutton switch 7 to indicate, by means of the bar graph 6, how severe is the symptom of concern on the 0-100% scale 14 (Figure 1) taking into consideration the indications 15.

Those skilled in the art will appreciate that a plurality of other messages such as questions can be contemplated to collect clinical data concerning a given patient and related to these messages. The present invention is in no way limited by the type of messages.

When no additional question is to be answered (step 29 of Figure 2), an "END" message is displayed on the alphanumeric display 4 (step 30 of

Figure 2). The patient then turns the data-logger device 1 off (step 31 of Figure 2).

The V.A.S. data collected in the memory 9 can be retrieved by the outside personal computer 12 through the RS 232 port interface 11 and through appropriate commands transmitted to the central processing unit 2. The collected data can then be processed as desired in the computer 12.

The dimensions of the portable data-logger device 1 are as reduced as possible to be easily carried by the examiner. Acceptable dimensions are those of an electronic calculator.

Although the present invention has been described hereinabove by way of a preferred embodiment thereof, this embodiment can be modified at will, within the scope of the appended claims, without departing from the spirit and nature of the subject invention.

WHAT IS CLAIMED IS:

1. A portable, interactive data-logger device for recording clinical data relative to a patient under investigation, comprising:

timer means for signalling to the patient a succession of recording time periods spaced apart by predetermined time intervals;

means for communicating a message to the patient after a recording time period has been signalled;

data-entering means for allowing the patient to enter clinical data relative to the patient and related to the message; and

memory means for receiving and storing the entered clinical data.

2. A portable, interactive data-logger device as recited in claim 1, in which said message communicating means comprises a display unit for displaying a question to be answered by the patient.

3. A portable, interactive data-logger device as recited in claim 1, further comprising means for turning the data-logger device on, wherein said message communicating means comprises means for

communicating a message to the patient following turning on of the data-logger device.

4. A portable, interactive data-logger device as recited in claim 1, further comprising means for preventing the patient to enter or alter any data entered during one of said recording time periods after said recording time period has elapsed.

5. A portable, interactive data-logger device as recited in claim 1, wherein:

said message communicating means comprises means for asking to the patient what intensity of pain he is feeling; and

said data-entering means comprises means for allowing the patient to enter the intensity of pain he is feeling.

6. A portable, interactive data-logger device as recited in claim 5, wherein said means for allowing the patient to enter the intensity of pain he is feeling comprises:

- a bar graph;
- pain intensity scale means along said bar graph; and
- pushbutton means for controlling said bar graph.

7. A portable, interactive data-logger device as recited in claim 1, wherein:

said message communicating means comprises means for asking to the patient what degree of discomfort he is feeling; and

said data-entering means comprises means for allowing the patient to enter the degree of discomfort he is feeling.

8. A portable, interactive data-logger device as recited in claim 7, wherein said means for allowing the patient to enter the degree of discomfort he is feeling comprises:

- a bar graph;
- discomfort degree scale means along said bar graph; and
- pushbutton means for controlling said bar graph.

9. A portable, interactive data-logger device as recited in claim 1, wherein:

said message communicating means comprises means for asking to the patient how severe is a given symptom; and

said data-entering means comprises means for allowing the patient to enter the severeness of said given symptom.

10. A portable, interactive data-logger device as recited in claim 9, wherein said means for allowing the patient to enter the severeness of said given symptom comprises:

- a bar graph;
- symptom severeness scale means along said bar graph; and
- pushbutton means for controlling said bar graph.

11. A portable, interactive data-logger device as recited in claim 1, wherein:

said message communicating means comprises means for asking to the patient both what intensity of pain and what degree of discomfort he is feeling; and

said data-entering means comprises means for allowing the patient to enter both the intensity of pain and the degree of discomfort he is feeling.

12. A portable, interactive data-logger device as recited in claim 11, wherein said means for allowing the patient to enter the intensity of pain and the degree of discomfort he is feeling comprises:

- a first bar graph;
- pain intensity scale means along said first bar graph;
- first pushbutton means for controlling said first bar graph;

- a second bar graph;
- discomfort degree scale means along said second bar graph; and
- second pushbutton means for controlling said second bar graph.

13. A portable, interactive data-logger device as recited in claim 1, comprising means for programming the time intervals between the successive recording time periods.

14. A portable, interactive data-logger device as recited in claim 1, comprising means for programming the message to be communicated to the patient after a recording time period has been signalled.

15. A portable, interactive data-logger device as recited in claim 1, wherein said message communicating means comprises means for communicating to the patient a plurality of messages, and wherein said data-entering means comprises means for allowing the patient to enter clinical data related to each of said messages.

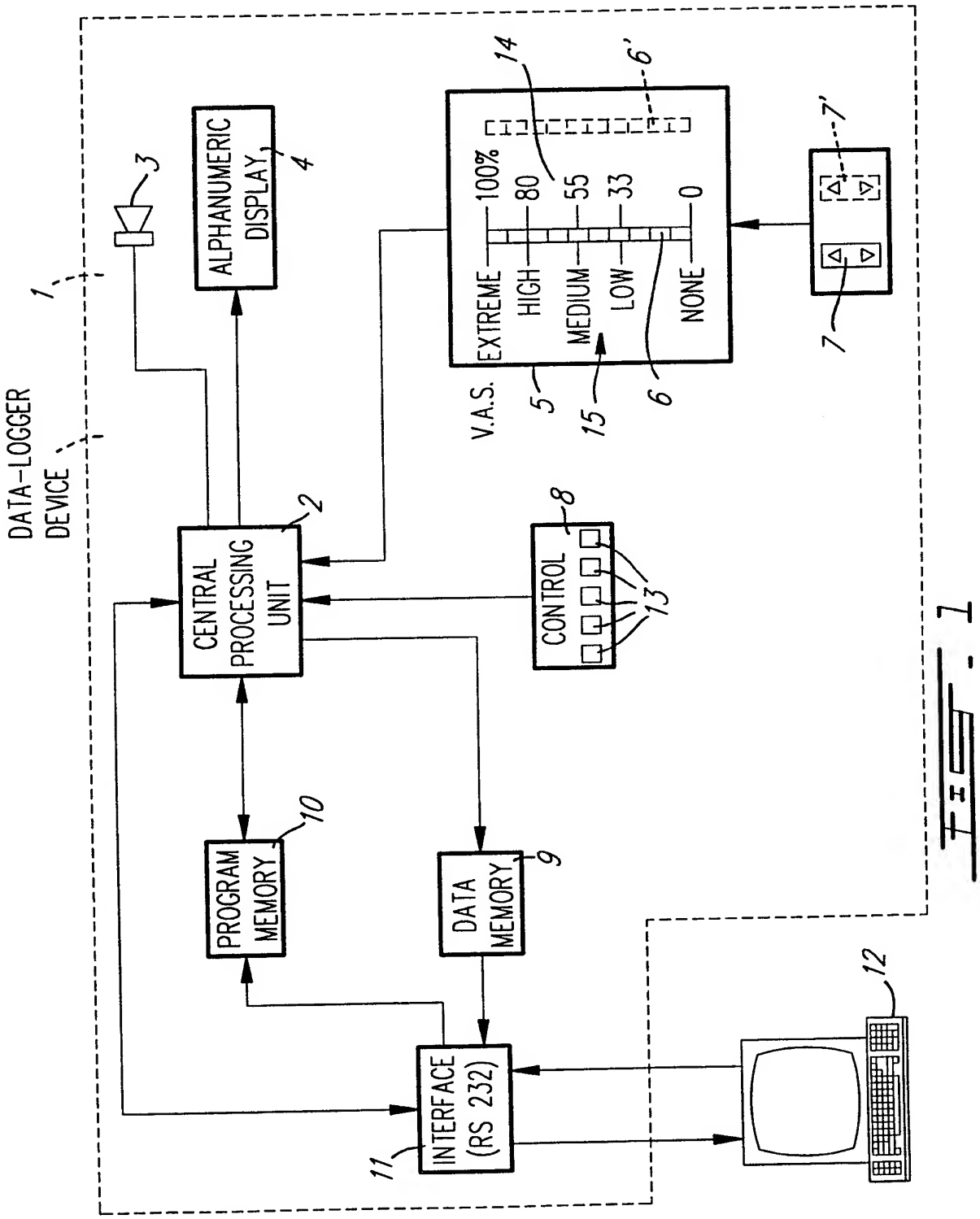

DATA-LOGGER DEVICE
1
CENTRAL PROCESSING UNIT
2
3
ALPHANUMERIC DISPLAY
4
V.A.S.
5
6
6'
7
7'
8
CONTROL
9
DATA MEMORY
10
PROGRAM MEMORY
11
INTERFACE (RS 232)
12
13
14
15
100%
80
55
33
0
EXTREME
HIGH
MEDIUM
LOW
NONE

Fig. 1

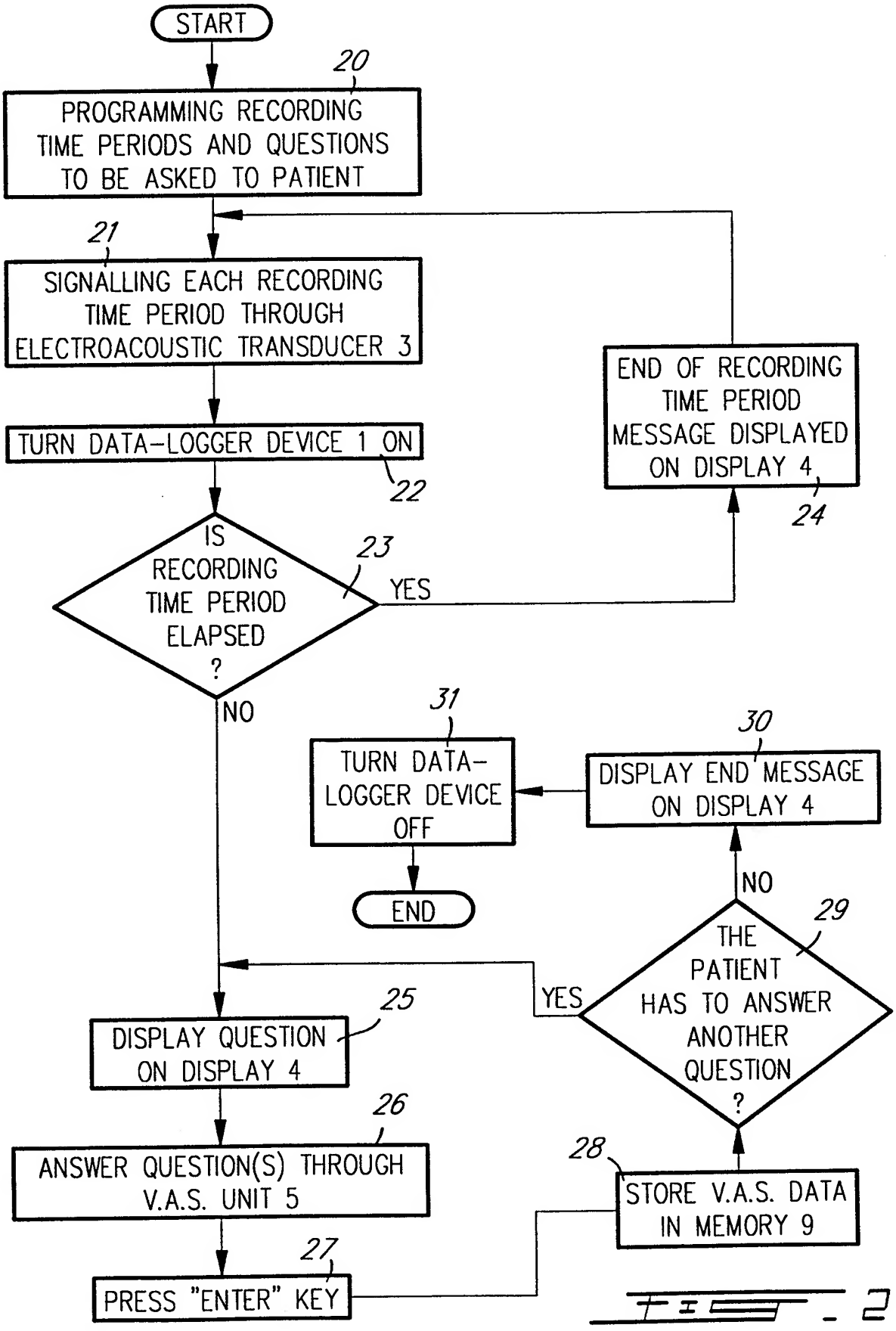

START
20
PROGRAMMING RECORDING TIME PERIODS AND QUESTIONS TO BE ASKED TO PATIENT
21
SIGNALLING EACH RECORDING TIME PERIOD THROUGH ELECTROACOUSTIC TRANSDUCER 3
TURN DATA-LOGGER DEVICE 1 ON
22
IS RECORDING TIME PERIOD ELAPSED ?
23
YES
END OF RECORDING TIME PERIOD MESSAGE DISPLAYED ON DISPLAY 4
24
NO
31
TURN DATA-LOGGER DEVICE OFF
END
30
DISPLAY END MESSAGE ON DISPLAY 4
NO
29
THE PATIENT HAS TO ANSWER ANOTHER QUESTION ?
YES
25
DISPLAY QUESTION ON DISPLAY 4
26
ANSWER QUESTION(S) THROUGH V.A.S. UNIT 5
27
PRESS "ENTER" KEY
28
STORE V.A.S. DATA IN MEMORY 9

FIG. 2

INTERNATIONAL SEARCH REPORT

Interna .al Application No
PCT/CA 97/00544

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 96 29007 A (WALKER DAVID JOHN) 26 September 1996	1
A	see page 10, line 12 - page 11, line 16 see page 13, line 11 - page 18, line 7 see page 21, line 18 - page 22, line 15; tables 1-3,11	5-8,10, 13,14

Y	EP 0 212 278 A (CARDIAC MONITORING SERV INC) 4 March 1987	1
A	see page 9, line 4 - page 34, line 16; table 1	2,3,15

A	FR 2 727 850 A (ELA MEDICAL SA) 14 June 1996 see abstract see page 5, line 16 - page 9, line 24; table 1	1,3,15

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
23 February 1998	12.03.98

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Weihs, J

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Interna .ial Application No
PCT/CA 97/00544

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 577 510 A (CHITTUM WILLIAM R ET AL) 26 November 1996 see column 4, line 32 - column 5, line 62; tables 1-3 -----	1,15

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern. ...nal Application No
PCT/CA 97/00544

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9629007 A	26-09-96	AU 5010896 A	08-10-96
		GB 2313672 A	03-12-97
EP 0212278 A	04-03-87	US 5012411 A	30-04-91
		AU 617862 B	05-12-91
		AU 4113189 A	14-12-89
		AU 587049 B	03-08-89
		AU 6047686 A	29-01-87
		CA 1287880 A	20-08-91
FR 2727850 A	14-06-96	NONE	
US 5577510 A	26-11-96	NONE	